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37 C.F.R. 1.8

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*Sept. 8, 2004*  
Date

*Paula S. Linkhart*  
Signature

**PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Stanislaw R. Burzynski

Serial No.: 09/863,035

Filed: MAY 22, 2001

For: TREATMENT REGIMEN FOR  
ADMINISTRATION OF  
PHENYLACETYLGLUTAMINE,  
PHENYLACETYLISSOGLUTAMINE  
AND/OR PHEYLACETATE

Confirmation No.: 1265

Group Art Unit: 1614

Examiner: COOK, REBECCA

Atty. Dkt. No.: 10379.0047.DVUS01

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

MS RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria VA, 22313-1450

Sir:

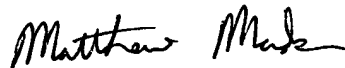
In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed are enclosed for the convenience of the Examiner (*i.e.* copies of documents C13–C15).

In accordance with 37 C.F.R. §§ 1.97(g),(h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Supplemental Information Disclosure Statement is submitted, under 37 C.F.R. §1.114(c) as part of a request for continued examination and is therefore to be timely filed in accordance with 37 C.F.R. § 1.97(b)(4). Thus, no fees are believed to be due in connection with the filing of this Supplemental Information Disclosure Statement, however, should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct said fees from Deposit Account No. 01-2508/10379.0047.DVUS01

Applicant respectfully requests that the listed documents be made of record in the present case.

Respectfully submitted,



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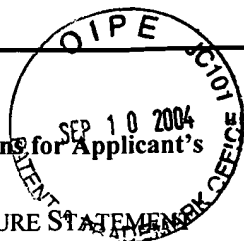
Date: Sept. 8, 2004

Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.  
BURG047--1/KAMSerial No.  
09/863,035Applicant  
STANISLAW R. BURZYNSKIFiling Date:  
May 22, 2001Group:  
1614U.S. Patent Documents  
*See Page 1*Foreign Patent Documents  
*See Page 1*Other Art  
*See Page 1*

## U.S. Patent Documents

| Exam. Init. | Ref. Des. | Document Number | Date | Name | Class | Sub Class | Filing Date of App. |
|-------------|-----------|-----------------|------|------|-------|-----------|---------------------|
|             | A5        |                 |      |      |       |           |                     |
|             | A6        |                 |      |      |       |           |                     |

## Foreign Patent Documents

| Exam. Init. | Ref. Des. | Document Number | Date | Country | Class | Sub Class | Translation Yes/No |
|-------------|-----------|-----------------|------|---------|-------|-----------|--------------------|
|             | B3        |                 |      |         |       |           |                    |
|             | B4        |                 |      |         |       |           |                    |

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

| Exam. Init. | Ref. Des. | Citation  |
|-------------|-----------|---|
|             | C13       | Waldbillig, Robert, J., "Pharmacokinetics of ANTINEOPLASTON A-10 and AS2-1 in patients with neoplastic disease" Report filed with FDA March 14, 1997  |
|             | C14       | Waldbillig, RJ, Patil, S, and Burzynski, SR "Uptake and intracellular binding of the antineoplastic agents phenylacetic acid (PN) and phenylacetylglutamine (PG): Effects on epigenetic mechanisms of gene regulation and gene expression", Report filed with FDA on May 26, 2004 |
|             | C15       | Burzynski, Janicki, Weaver, Jurida, Szymmkowski, Khan, and Dolgoplov, "Clinical application of body epigenetic system: multi-targeted therapy for primary brain tumors" Poster at the World Conference on Dosing of Antiinfectives, Nuremberg, Germany, September 9-11, 2004.     |

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)